Summary of ACE/ITDS Pilot Standard Operating Procedures (SOP): Food and Drug Administration (FDA)

Objective: FDA is developing a message set and processes to support the electronic submission of data for FDA's needs in the ACE environment. In order to test the developed message set and processes, CBP and FDA will engage, together with the trade community, in a pilot to test the new system as it is used by both CBP and FDA operations in real time with actual ACE filings in the production environment.

The Partner Government Agency (PGA) Message Set now permits FDA to collect all of the data required by its statutory mandates, which could not be captured in the limited ACS/OASIS interface. FDA deleted its FDA Entry 701 Form many years ago and to date collects its import data elements under the CBP's Form 3461. Therefore, there are no FDA forms that need to be collected electronically through ACE. FDA will require all data needed for cargo admissibility under ACE/ITDS to be under the auspices of the PGA Message Set. When entry data is received by FDA, it will perform validation of the data, conduct its cargo admissibility process and send cargo disposition messages back through ACE to the filer.

Scope: Transition from ACS to PGA Message Set

Import Statutory Authority	Commodity Description	Collected Using the PGA Message Set	Using DIS	CFR Citation for applicable regulations
801(a)	All FDA-regulated commodities	Y	N*	Numerous under 21 CFR
801(m)	Food products requiring Prior Notice	Y	N*	21 CFR 1.276 – 1.285

*FDA will continue to use its Import Trade Auxiliary Communication System (ITACS) until DIS can operate at the line level.

Ports (Phases 1, 2, 3, & 4): FDA plans to expand its pilot according to CBP's port expansion schedule. As CBP makes ports eligible for filing, FDA's pilot parameters will expand to include the applicable ports.

For Technical Specifications click on the following link:
http://www.cbp.gov/trade/automated/systems